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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,605	05/31/2002	Ulrike Fiedler	1406/37	8368

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EXAMINER	
LEE, MATTHEW C	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,605	FIEDLER ET AL.	
	Examiner	Art Unit	
	Matthew C Lee	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/03/2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, 26-28, and 42, drawn to protein with beta-sheet structure, classified in class 530, subclass 324.

II. Claims 17-18, and 36-41, drawn to polynucleotide, vectors, host cells, and method of expressing proteins using said vectors and host cells, classified in class 435, subclass 320.1

III. Claims 20-24, and 29-35, drawn to a method of preparing proteins with beta-sheet structures, classified in class 435, subclass 69.1.

IV. Claim 25, drawn to a method of preparing a chemical composition, classified in class 435, subclass 69.1.

V. Claims 43-45, drawn to a method of preparing a gamma crystalline protein with a new binding property, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other for the following reasons:

1. Inventions I and II are patentably distinct products. Group I is separated and distinct from group II because the inventions are directed to different chemical types regarding the critical limitations therein. For group II, the critical feature is a polynucleotide whereas for group I the critical feature is a polynucleotide. It is

acknowledged that various processing steps may cause a polynucleotide of group II to be directed as to its synthesis by a polynucleotide of group I, however, the completely separate chemical types of the inventions of Group I and II supports the undue search burden if both were searched together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if searched together, as compared to being search separately. Also, it is pointed out that although processing may connect two groups, such a connection does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc., therefore, these two groups of inventions are separate and distinct.

2. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the beta-sheet proteins can also be made by synthetic methods that do not require the recombinant method of invention III.

3. Invention I and IV are separate and distinct inventions. Invention IV is a method that uses the product of invention I as an ingredient to make another product. They are patentably distinct because the product of invention I can be used in materially different processes (e.g. as an ingredient in making fluorescent paint).

4. Invention I and V are not related. In this instant case, the protein of Invention I is not limited to be one produced by the method of Invention V; the method of Invention V does not recite production of a protein with a "beta-sheet structure" as in Invention I, thus the method of invention I is patentably distinct from the product of invention V.

5. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of invention II can also be used in methods of hybridization, PCR analysis, RFLP analysis, etc. Therefore, they are patentably distinct inventions.

6. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention II is directed to polynucleotides, hosts and vectors whereas invention IV is directed to a method of preparing a chemical composition comprising beta-sheet proteins which have different structure, function and effects from the polynucleotides, hosts, vectors, etc.

7. Inventions II and V are unrelated. In this instant case, invention II is directed to polynucleotides, hosts and cells whereas invention V is directed to a method of making gamma crystalline proteins. Invention V does not recite the use of the polynucleotide of

Invention II and the product of invention II can have a range of materially different uses (see 4). Therefore invention II and V are unrelated inventions.

8. Invention III and IV are two distinct methods. They each recite different method steps, achieve different effects and produce different products (a composition vs. a protein), and are therefore, separate and distinct inventions.

9. Invention III-V are each separate and distinct from one the other because they each recites different method steps, makes different products and achieves different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the search required for each group are not coextensive and creates an undue search burden as indicated by their different classification and divergent subject matter, restriction for examination purposes is proper.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed inventions. If applicant elects group I, applicant is required to elect a single embodiment of the claimed invention that specifies each of the following:

A. a single species of crystalline protein (e.g. claim 8)

B. a single type of property from binding or catalysis (e.g. claim 13).

C. a single species of vertebrate (e.g. claim 26).

If applicant elects group III, applicant is required to elect a single embodiment of the claimed invention that specifies each of the following:

A. a single expression system selected from prokaryotic, eukaryotic, or cell-free (e.g. claim 22).

B. a single type of expression entity selected from plant cell, animal cell, yeast cell, virus or bacterium (e.g. claim 30).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Sequence Election Requirement

In addition, this application contains group(s) that read on patentably distinct group(s) drawn to multiple sequences/SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore a further restriction is applied to each Group. For an elected Group drawn to either amino acid or polypeptide sequences, the applicant must further elect a **single** amino acid or a **single** polypeptide sequence. (See MPEP 803.04). Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, the requirements of 37 CFR 1.141 et seq. are no longer waived and applicant is required to elect a single sequence for examination. Applicant is reminded that this is a restriction requirement, not an election of species.

If applicant elects group I, applicant is further required to elect a single protein for examination (e.g. claim 2).

If applicant elects group II, applicant is further required to elect a single SEQ ID for examination (e.g. claims 39 and 41).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew C Lee whose telephone number is (571) 272-2931. The examiner can normally be reached on 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P WOODWARD can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew C. Lee, Ph.D.
08/26/2004

MARJORIE MORAN
PATENT EXAMINER
Marjorie A. Moran
9/16/04